ENCLOSURES FOR

EPA-HQ-2018-001919

J. Benton Hurst, Esq.

Glyphosate

Duffy, Rick

From: [redacted]
Sent: Tuesday, March 17, 2015 8:46 AM
To: [redacted], Rick [redacted] Ex6
Subject: FW: GLP Certification
Attachments: image001.jpg

Importance: [redacted] High

Do you need anything from me for the MAMPD General with Betsy when the e-mail from Cynthia is discussed?

From: [redacted] Ex6
Sent: Tuesday, March 17, 2015 7:45 AM
To: [redacted] Ex6
Subject: FW: GLP Certification

Hi [redacted] Ex6
Got your email on this. I suggest we wait on preparing a response until Ed speaks with Betsy and others.
[redacted] Ex6

From: [redacted] Ex6
Sent: Monday, March 16, 2015 9:18 PM
To: [redacted] Ex6
Subject: Fwd: GLP Certification

Fyi you mentioned something about this to me.

Sent from my iPhone

Begin forwarded message:

From: [redacted] Ex6
Date: March 16, 2015 at 6:58:57 PM EDT
To: [redacted], "Duffy, Rick" <Duffy.Rick@epa.gov>, Ex 6
[redacted] Ex6
Cc: " [redacted] Ex6
Subject: FW: GLP Certification

Please add this to your weekly this week. We should also plan on circling back to Cynthia next week or by email.

From: Giles-AA, Cynthia
Sent: Monday, March 16, 2015 5:54 PM
To: [redacted]
Cc: [redacted] Ex6
Subject: FW: GLP Certification

Ex 6 = Exemption 6

From: [redacted] Ex6
Sent: Monday, March 16, 2015 2:51 PM
To: [redacted] Ex6
Cc: [redacted]s-AA, Cynthia Ex6
Subject: RE: GLP Certification

[redacted], I am forwarded your message to my colleague in the [redacted] Ex6 has responsibility for the issue you have raised. Thanks. Ex6

From: [redacted] Ex6
Sent: Monday, March 16, 2015 10:29 AM
To: [redacted] Ex6
Subject: RE: GLP Certification

I never heard back from you about this. Can we please schedule a time to s[redacted]

[redacted]

From: [redacted] Ex6
Sent: Saturday, February 28, 2015 6:55 AM
To: [redacted] Ex6
Subject: GLP Certification

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>
> Yours sincerely,
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Ex6 = Exemption 6

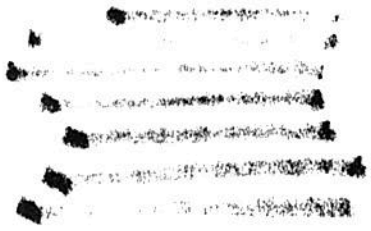
I have been with [redacted] and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it. Ex 6

Best regards

[redacted] Ex 6

- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

Ex 6 = Exemption 6



Duffy, Rick

From: [redacted] Ex6
Sent: [redacted] Ex6 Monday, March 16, 2015 6:59 PM
To: [redacted] Duffy, Rick; Ex6
Cc:
Subject: FW: GLP Certification

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Please Visit us at Booth # 1701

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To: [redacted] Duffy, Rick EX6
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It would be great to use the GLP slides for briefing Cynthia right?

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U.S. EPA
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
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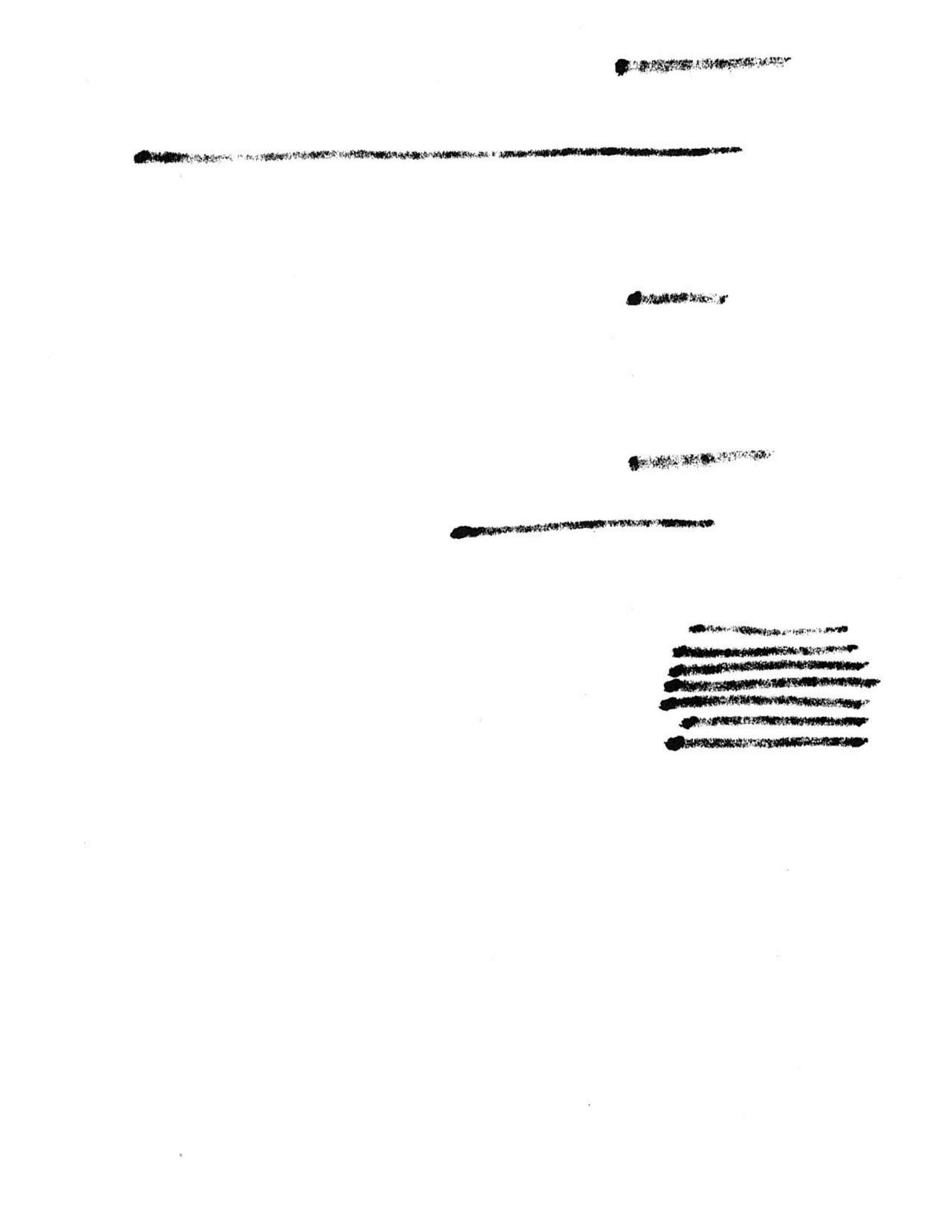

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To: [redacted]; Duffy, Rick Ex6
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Subject: RE: GLP Certification

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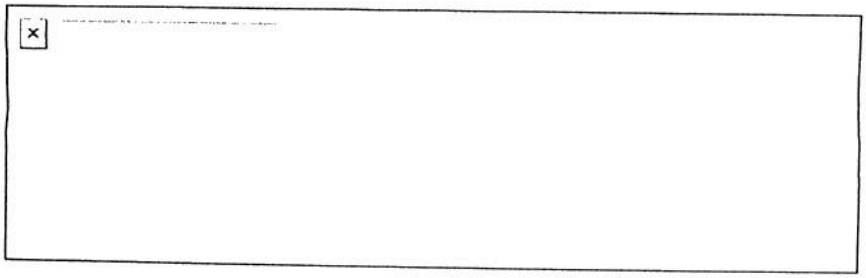

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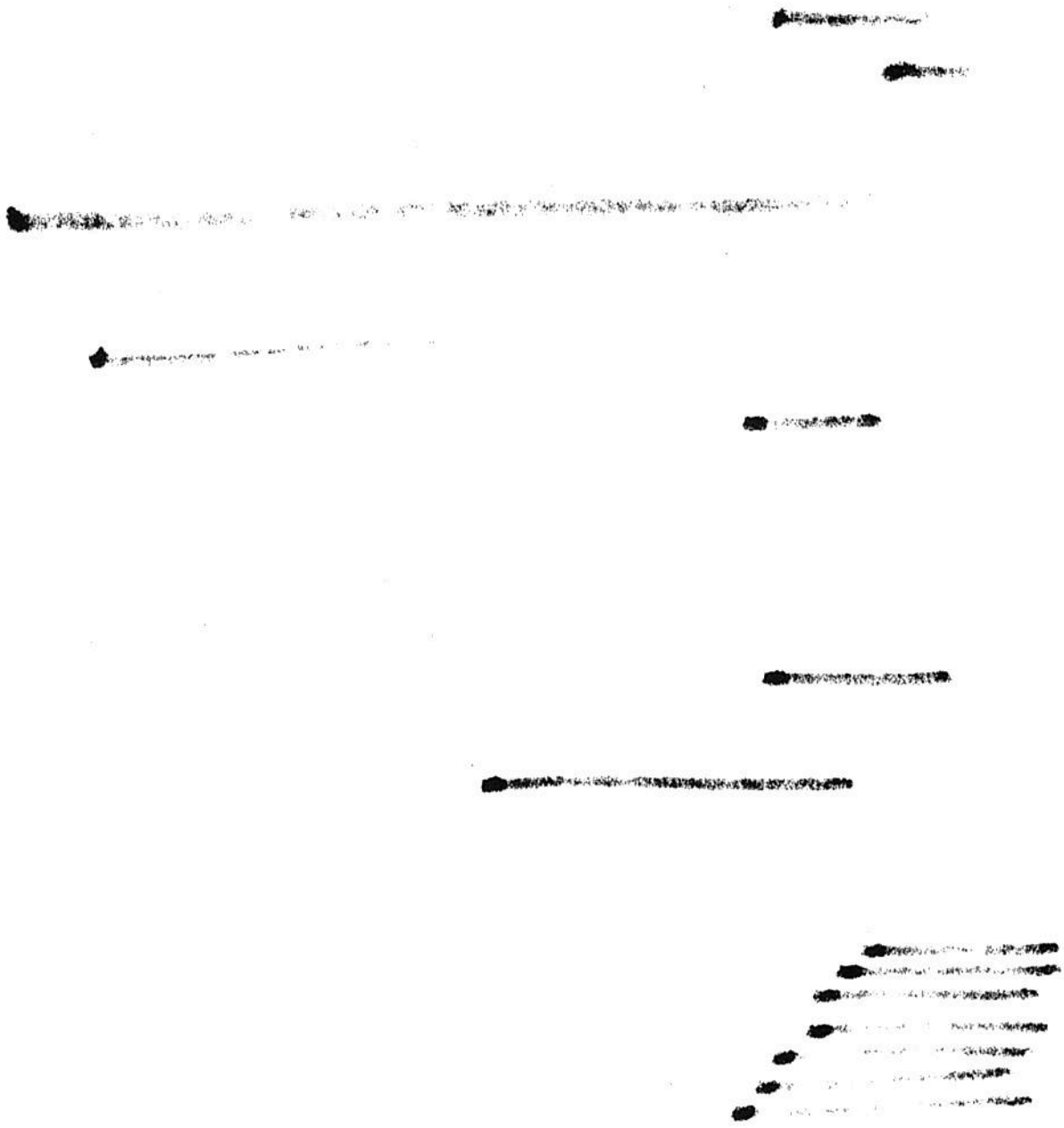

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Ex6 [redacted] asked to talk about the email from the lab complaining to [redacted] Ex6 at the weekly so please attend to speak to that. I know [redacted] so [redacted] can we try to have [redacted] speak first or at the beginning? Ex6 [redacted]

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Ex6 = Exemption 6

- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
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- GLP Analytical Chemistry
- Antimicrobial Efficacy

Duffy, Rick

From: [redacted] Ex6
Sent: Thursday, March 19, 2015 9:01 AM
To: [redacted] Duffy, Rick Ex6
Subject: FW: From Weekly
Attachments: response.docx; Briefing for [redacted]2.12.15 version.pptx; Ex6 ki Letter.Briefing for Cynthia Giles.docx

For your review, comment and/or approval, attached you will find:

(1) Draft response to [redacted] email to [redacted] Ex6
(2) Draft Briefing Paper for Cynthia Giles on the Wnorowski email to [redacted] Ex6
(3) Slides – At your request, the 50+ original slides were reviewed and 17 were selected to fit the time allotment for the briefing.

[redacted] } Ex6

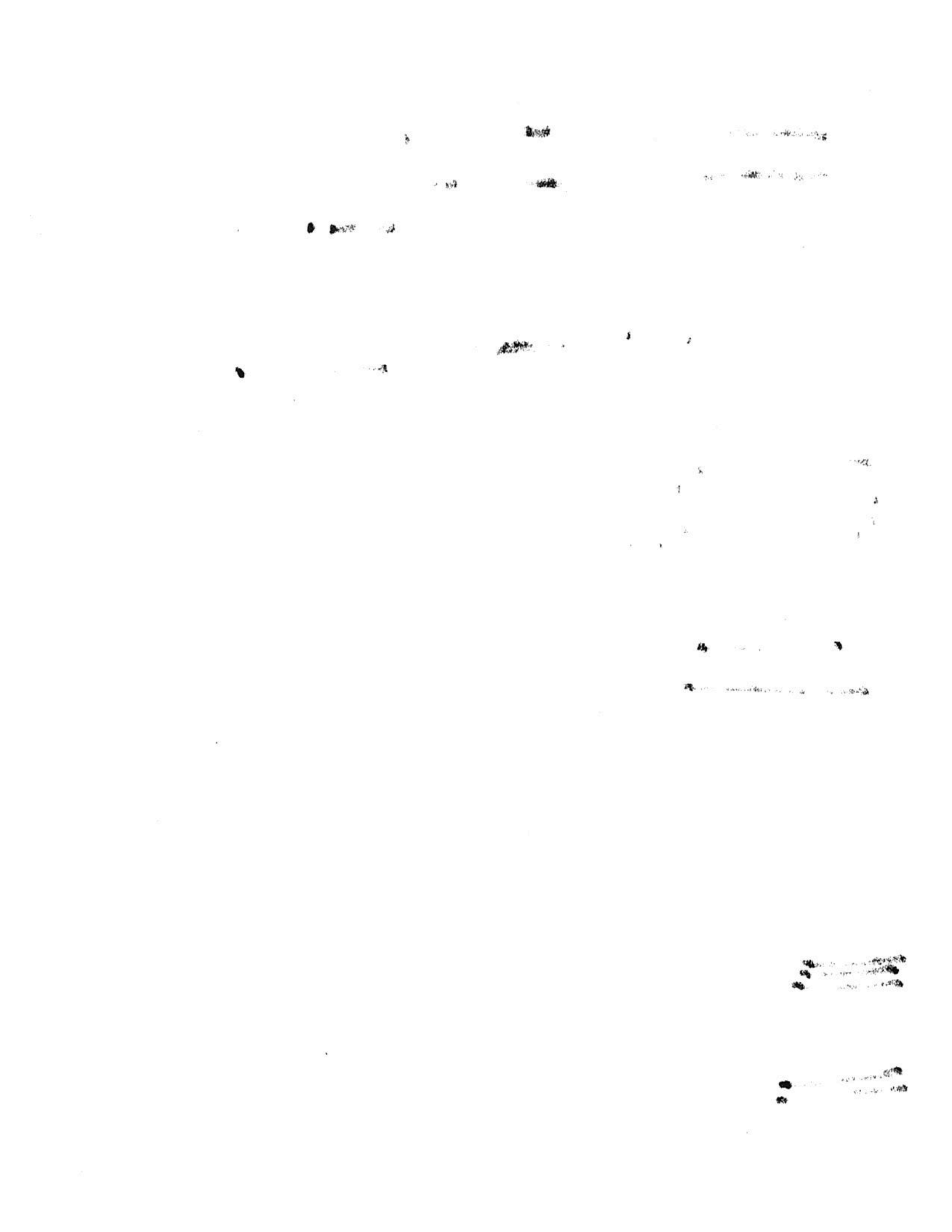
From: [redacted] Ex6
Sent: Wednesday, March 18, 2015 5:41 PM
To: [redacted] Ex6
Cc: Duffy, Rick;
Subject: From Weekly

Prepare response to lab letter on GLP certifications.
Put on weekly for next week with Cynthia.
Finish GLP slides for Cynthia asap.

Tx.

[redacted] } Ex6
U.S. EPA
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
[redacted]

Ex 6 = Exemption 6



Draft Response to Incoming Email:

Dear Mr. [redacted] Ex6

Your email to [redacted] Ex6 has been forwarded to me for response. As [redacted] Ex6 indicated in [redacted] email to you, [redacted] Ex6 Ex6 As such, I sincerely appreciate receiving feedback from members of the GLP community and recognize the issues and concerns raised in your email.

I understand your frustration. However, I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, [redacted] Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the issuance of certifications. The GLP program is based on existing statutory and regulatory authorities, which authorize a compliance monitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data program.

If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged.

[redacted]

Sincerely,

[redacted] Ex6 [redacted]

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I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

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Briefing for Cynthia Giles

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Quick Response:

Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.

Ex 6 = Exemption 6

Overview of the Current FIFRA GLP Program

EPA's GLP Program is a quality management system used to ensure the integrity and validity of scientific studies and data generated and submitted as part of pesticide or chemic[redacted] under FIFRA. EPA does not test pesticides to support registrations. Rather, EPA relies on studies performed by or for applicants for registration. Laboratories are sometimes owned by the registrant but can also be independently operated and hired by the registrant. It is not required for the laboratory to be certified, however, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations, which requires laboratory personnel to have adequate education, training and experience to conduct the study.

The GLP regulation, 40 CFR Part 160, covers a wide variety of areas including equipment maintenance and calibration, testing operations, test substances, study protocols, the conduct of a study, recordkeeping and reporting requirements as well as testing facility management[redacted]rtant feature of the GLP regulation is the Statement of compliance or non-compliance. 40 CFR 160.12. Any person who submits an application to EPA for a research or marketing permit that contains a study must submit a true and correct statement, signed by the applicant, the sponsor of the study and the study director. The statement must contain one of three listed assertions: (1) whether the study was conducted in accordance with GLP rule or (2) all the differences between the practices used in the study and those required by the GLP rule or (3) the signatory was not a sponsor or the study, did not conduct the study and does not know whether the study was conducted in accordance with th[redacted]

An NAIS inspection will include an on-site facility compliance review as well as a data audit. A data audit is where a study is selected and reviewed by the ins[redacted]he study is consistent with the final report that was submitted to EPA. The NAIS uses a random selection process or the Laboratory Information and Study Audit (LISA) database that screens for the following neutral criteria:

- Labs that have submitted the most number of studies to EPA in the last [redacted]
- Labs that had major GLP findings in a previous inspection,
- Labs that have initiated testing under FIFRA or TSCA for the first [redacted]
- Labs that have submitted a study that is expected to form the ba[redacted] action,
- Labs that have not been inspected for the last 3 years,
- Labs located in geographic proximity to other laboratories.

Currently, the only sections of FIFRA that would address violations of the GLP regulations is FIFRA Section 12(a)(2)(M)(Q) and (R). All are based on submissions to the Agency. The most common enforcement action concerns the submission of a false 160.12 compliance statement where the submitter attests that a study was conducted in accordance with GLP regulations, but deviations were found during the inspections. If this statement is false, a civil or criminal enforcement response may be

pursued by the Agency. There are no other bases for initiating an enforcement action for a violation of the GLP regulations. In the case of missing raw data, an enforcement action can be initiated for violating 40 CFR Part 169. GLP violations can result in the rejection of a study by EPA and, therefore, a denial of a registration application.

The GLP Program is affected by EPA's membership in the Organization for Economic Cooperation and Development (OECD). As an OECD member, EPA subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program benefits the United States economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

Duffy, Rick

From: [redacted] Ex6
Sent: Monday, March 23, 2015 1:30 PM
To: [redacted] Duffy, Rick Ex6
Subject: FW: From Weekly
Attachments: response.docx; Briefing for Letter.Briefing for Cynthia Giles.docx

Let me know if you agree with response. Tx.

[redacted]

[redacted] Ex6

U.S. EPA
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
[redacted] Ex6

From: [redacted] Ex6
Sent: Monday, March 23, 2015 12:34 PM
To: [redacted]
Subject: FW: From Weekly

[redacted] Ex6

Here is the incoming letter and our proposed response for your approval.

[redacted]

From: [redacted] Ex6
Sent: Friday, March 20, 2015 10:53 AM
To: [redacted] Ex6
Subject: FW: From Weekly

[redacted]

Apparently you were not on the distribution list.

From: [redacted] Ex6
Sent: Thursday, March 19, 2015 9:01 AM
To: [redacted] Duffy, Rick Ex6
Subject: FW: From Weekly

For your review, comment and/or approval, attached you will find:

Ex6 = Exemption

(1) Draft response to Wnorowski email to Jim Jones,
(2) Draft Briefing Paper for Cynthia Giles on the Wnorowski email to [redacted] EX6
(3) Slides – At your request, the 50+ original slides were reviewed and 17 were selected to fit the time allotment for the briefing.

[redacted]

EX6

From [redacted] EX6
Sent: Wednesday, March 18, 2015 5:41 PM
To [redacted] EX6
Cc: Duffy, Rick [redacted] EX6
Subject: From Weekly

Prepare response to lab letter on GLP certifications.
Put on weekly for next week with Cynthia.
Finish GLP slides for Cynthia asap.

Tx.

[redacted] EX6

U.S. EPA
1200 Pennsylvania Ave., N.W. (MC-2227A)
Washington, DC 20460
[redacted] EX6

Exemption 6
EX6=

Duffy, Rick

From: [redacted] Ex6
Sent: Friday, March 27, 2015 3:05 PM
To: [redacted] Duffy, Rick Ex6
Subject: RE: From Weekly
Attachments: [redacted]ponse lizcmt.docx [redacted]

[redacted] and [redacted] Ex6

Please see my comments on the email response. Let me know if anything is not accurate.

[redacted] Ex6

From: [redacted] Ex6
Sent: Thursday, March 19, 2015 9:01 AM
To: [redacted] Duffy, Rick Ex6
Subject: FW: From Weekly

For your review, comment and/or approval, attached you will find:

(1) Draft response to Wnorowski email to [redacted] Ex6
(2) Draft Briefing Paper for Cynthia Giles on the Wnorowski email to Jim Jones,
(3) Slides – At your request, the 50+ original slides were reviewed and 17 were selected to fit the time allotment for the briefing.

[redacted] Ex6

From [redacted] Ex6
Sent: Wednesday, March 18, 2015 5:41 PM
To [redacted] Ex6
Cc: Duffy, Rick [redacted] Ex6
Subject: From Weekly

Prepare response to lab letter on GLP certifications.
Put on weekly for next week with Cynthia.
Finish GLP slides for Cynthia asap.

Tx.

Ex6 = Exemption 6

[redacted]

U.S. EPA
1200 Pennsylvania Ave., N.W.
[redacted]
Washington, DC 20460
[redacted]

Ex6

[redacted]

Ex 6 = Exemption 6

Draft Response to Incoming Email:

Dear [redacted] Ex6

Your email to [redacted]s has been forwarded to me for response. As [redacted] indicated in [redacted]mail to [redacted] Ex6 you, [redacted] Ex6 As such, I sincerely appreciate receiving feedback from members of the GLP community and recognize the issues and concerns raised in your email. I understand your frustration.

~~I understand your frustration. However~~, I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, neither the Federal Insecticide, Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the EPA to certify GLP laboratories in the US ~~the issuance of certifications~~. Instead, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations, which requires laboratory personnel to have adequate education, training and experience to conduct the study. A change in this framework will require changing the regulations. The GLP program is based on existing statutory and regulatory authorities, which authorize a compliance monitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data program.

If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged.

Sincerely,

[redacted] } Ex6

Incoming:

From: [redacted] Ex6
Sent: Monday, March 16, 2015 2:51 PM
To: [redacted] } Ex6
Cc: [redacted]
Subject: RE: GLP Certification

[redacted] Ex6 I am forwarded your message to my colleague in the Office of Enforcement and Compliance Assurance, Frances Liem. She has responsibility for the issue you have raised. Thanks. Jim

From: [redacted] Ex6
Sent: Monday, March 16, 2015 10:29 AM
To: [redacted] Ex6
Subject: RE: GLP Certification

[redacted] Ex6

Ex6 = Exemption 6

I never heard back from you about this. Can we please schedule a time to speak this week?

[redacted] Ex6 [redacted] [redacted]

[redacted]

From: [redacted] Ex6
Sent: Saturday, February 28, 2015 6:55 AM
To: [redacted] Ex6
Subject: GL[illegible]tion

I manage a contract lab that specializes in the conduct of toxicology and chemistry studies on pesticides for submission to global regulatory authorities for registration. We continue to be put at a significant competitive disadvantage in the industry because of EPA's resistance to issuing GLP certificates like every other OECD nation. Several times in the last few months we have lost projects to laboratories in other countries because of this issue. Just this morning, our [redacted] Ex6 s received the following email from a Chinese client.

> Dear [redacted] Ex6
> Good day!
> I am very sorry to tell you that we would not put the study of glyphosate ammonium in your lab. Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time.
>
> Yours sincerely,
> [redacted] Ex6
> Market&registration Division

[redacted]

I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

Best regards

[redacted] Ex6

[redacted]

Field Code Changed

[redacted]

Ex6 = Exemption 6

[redacted] 3 Ex4

- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

Ex6 = Exemption 6

Duffy, Rick

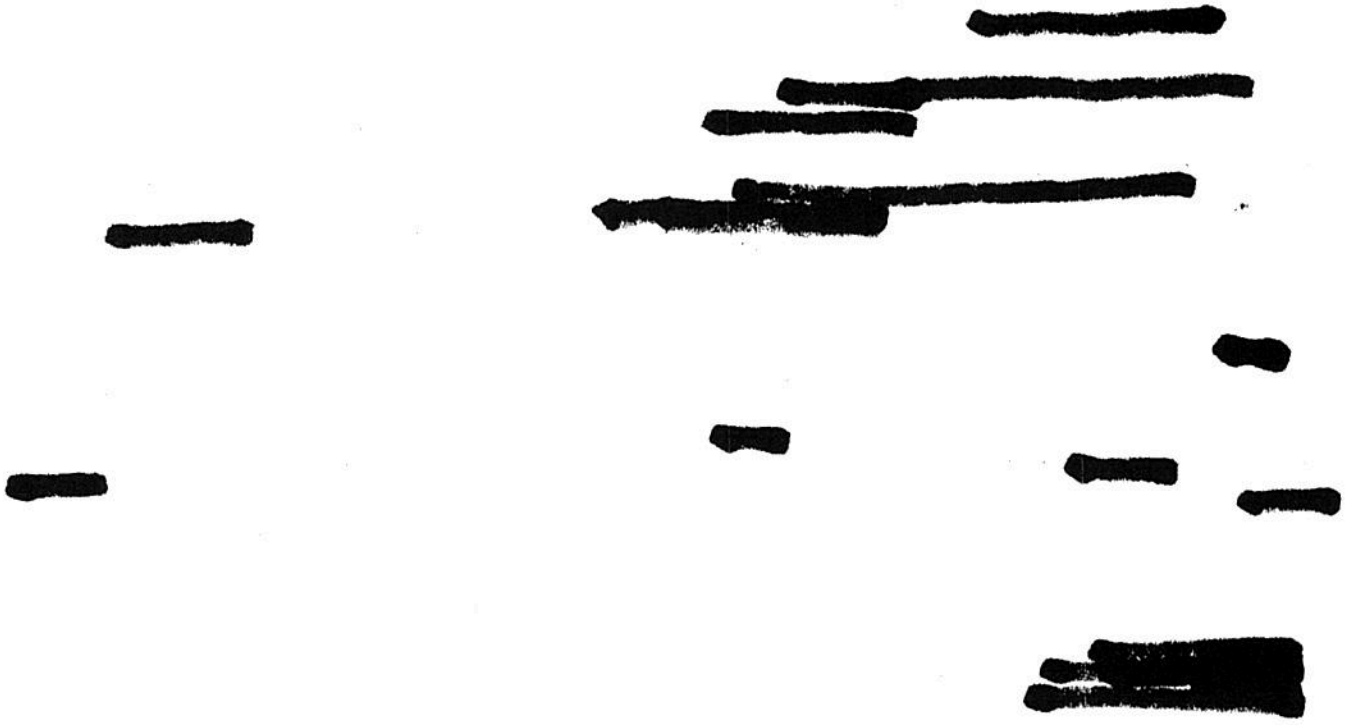
From: [redacted] Ex6
Sent: Monday, March 30, 2015 6:34 PM
To: [redacted] Ex6
Cc: [redacted], Duffy, Rick;
Subject: [redacted] Ex6 Request re GLP lab certification and email response for your review
Attachments: [redacted] Labs email response 3-30.docx; [redacted] etter and Response Why doesnt EPA issue GLP certificates to labs 3-18-15.docx Ex6

Hi [redacted] Ex6

A topic on the agenda for your weekly with [redacted] Ex6 Wednesday is "Request re GLP lab certification." The President of a lab emailed [redacted] Ex6, expressing concern about a competitive disadvantage. Jim forwarded the email to [redacted] and Ex6 [redacted] asking Francis to respond. Attached is an email response for your review and the original email as background. The second attachment is a more detailed background paper for [redacted] which again summarizes the incoming email from the lab, and explains the GLP program.

[redacted] Ex6

Ex6 = Exemption 6



Summary

- [redacted] emails [redacted] the email to [redacted] and [redacted] asking [redacted] to respond. [redacted]
- [redacted] expressed feeling at a competitive disadvantage because EPA does not issue FIFRA Good Laboratory Practice certificates to laboratories like other Organization for Economic Cooperation and Development (OECD) countries.
- It's true, EPA is the only OECD country with a GLP program that does not issue certificates to laboratories. The US GLP program is a quality management system used to validate studies and data generated and submitted as part of pesticide or chemical registration applications under FIFRA.
- Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.
- The GLP Program is affected by EPA's membership in the OECD. [redacted] subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program benefits the economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

[redacted] Draft Response to Incoming Email for [redacted] review:

Dear [redacted]

Your email to [redacted] has been forwarded to me for response. As [redacted] indicated in [redacted] mail to you, [redacted] As such, I sincerely appreciate receiving feedback from members of the GLP community and recognize the issues and concerns raised in your email. I understand your frustration.

I want to assure you that EPA is not resisting the issuance of GLP certificates, as you indicate in your email. As currently written, neither the Federal Insecticide, Fungicide and Rodenticide Act nor the Good Laboratory Practice regulations authorize the EPA to certify GLP laboratories in the US. Instead, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations. A change in this framework will require changing the regulations. The GLP program is based on existing statutory and regulatory authorities, which authorize a comp[redacted] monitoring and enforcement program to detect and deter violations of the regulations and to assist in regulatory decision-making. EPA's inspection program is accepted by OECD and, therefore, we do participate in the Mutual Acceptance of Data program.

If you would like to discuss your concerns or if you have any questions about EPA's GLP program, a teleconference can be arranged.

Sincerely,

[redacted]

Ex6 = Exemption 6

[redacted] Ex6

Background-Incoming email chain:

From: [redacted] Ex6
Sent: Monday, March 16, 2015 2:51 PM
To: [redacted] Ex6
Cc: [redacted] Giles-AA, Cynthia
Subject: RE: GLP Certification

Ex6
[redacted] I am forwarded your message to my colleague in the Office of Enforcement and Compliance Assurance, [redacted] has responsibility for the issue you have raised. Thanks. [redacted]

Ex6

From [redacted] Ex6
Sent: Monday, March 16, 2015 10:29 AM
To: [redacted] Ex6
Subject: RE: GLP Certification

[redacted] Ex6
I never heard back from you about this. Can we please schedule a time to speak this week?

[redacted]

From: [redacted] Ex6
Sent: Saturday. February 28, 2015 6:55 AM
To: [redacted] Ex6
Subject: GLP Certification

[redacted] Ex 6
I manage a contract lab that specializes in the conduct of toxicology and chemistry studies on pesticides for submission to global regulatory authorities for registration. We continue to be put at a significant competitive disadvantage in the industry because of EPA's resistance to issuing GLP certificates like every other OECD nation. Several times in the last few months, we have lost projects to laboratories in other countries because of this issue. Just this morning, our Director of Analytical Services received the following email from a Chinese client. [redacted]

Ex6 = Exemption 6

Dear [redacted] Ex6

Good day!

I am very sorry to tell you that we would not put the study of glyphosate ammonium in your lab. Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time.

Yours sincerely,

[redacted] Ex6

Market&registration Division

I have been with Product Safety Labs for over 25 years and have grown incredibly frustrated over this issue. I would like to know if you could be available for a short discussion by phone so that I could understand the agencies position on this issue and discuss possible ways to address it.

Best regards

[redacted] Ex6

- Repeated Dose Toxicology
- Reproductive/Developmental Toxicology
- Genetic Toxicology
- Environmental Toxicology
- Product Chemistry
- GLP Analytical Chemistry
- Antimicrobial Efficacy

Ex6 = Exemption 6

FIFRA GLP Laboratory Inspection
Briefing for Cynthia Giles

Summary

- [redacted] Ex 6 on Feb. 28, 2015 [redacted] Ex 6 sent the email to Cynthia and [redacted] Ex 6 GLP Section Chief. OECA's FIFRA GLP Section is within the Office of Compliance.
- [redacted] Ex 6 expressed feeling at a competitive disadvantage because EPA does not issue FIFRA Good Laboratory Practice certificates to laboratories like other Organization for Economic Cooperation and Development (OECD) countries.
- It's true, EPA is the only OECD country with a GLP program that does not issue certificates to laboratories.
- Currently, neither FIFRA nor the Good Laboratory Practice Regulations authorize the issuance of certifications. The existing GLP inspection program constitutes a compliance monitoring and enforcement program to detect and deter violations of the GLP regulations and to assist in regulatory decision-making.
- The GLP Program is affected by EPA's membership in the OECD. As an OECD member, EPA subscribes to the Mutual Acceptance of Data (MAD) program. The MAD program requires OECD members to accept data from each other for review. This program benefits the United States economy by making it easier for pesticide and chemical companies to engage in international trade. To be part of the MAD program, EPA must have a valid and active GLP Compliance Monitoring Program and conduct inspections. A certification program is not required.

Background-Overview of the Current FIFRA GLP Program

EPA's GLP Program is a quality management system used to ensure the integrity and validity of scientific studies and data generated and submitted as part of pesticide or chemical registration applications under FIFRA. EPA does not test pesticides to support registrations. Rather, EPA relies on studies performed by or for applicants for registration. Laboratories are sometimes owned by the registrant but can also be independently operated and hired by the registrant. It is not required for [redacted]ory to be certified, however, studies that are submitted to EPA in support of registration applications must be conducted in accordance with the GLP regulations, which requires laboratory personnel to have adequate education, training and experience to conduct the study.

The GLP regulation, 40 CFR Part 160, covers a wide variety of areas including equipment maintenance and calibration, testing operations, test substances, study protocols, the conduct of a study, recordkeeping and reporting requirements as well as testing facility management. An important feature of the GLP regulation is the Statement of compliance or non-compliance. 40 CFR 160.12. Any person who submits an application to EPA for a research or marketing permit that contains a study must submit a true and correct statement, signed by the applicant, the sponsor of the study and the study director. The statement must contain one of three listed assertions: (1) whether the s[redacted]nducted in

Ex 6 = Exemption 6

accordance with GLP rule or (2) all the differences between the practices used in the study and those required by the GLP rule or (3) the signatory was not a sponsor or the study, did not conduct the study and does not know whether the study was conducted in accordance with the GLP rule.

An NAIS inspection will include an on-site facility compliance [redacted] as a data audit. A data audit is where a study is selected and reviewed by the inspector to verify that the data from the study is consistent with the final report that was submitted to EPA. The NAIS uses a random selection process or the Laboratory Information and Study Audit (LISA) database that screens for the following neutral criteria:

- Labs that have submitted the most number of studies to EPA in the last 3 years,
- Labs that had major GLP findings in a previous inspection,
- Labs that have initiated testing under FIFRA or TSCA for the first time,
- Labs that have submitted a study that is expected to form the basis for a major regulatory action,
- Labs that have not been inspected for the last 3 years,
- Labs located in geographic proximity to other laboratories.

Currently, the only sections of FIFRA that would address violations of the GLP regulations is FIFRA Section 12(a)(2)(M)(Q) and (R). All are based on submissions to the Agency. The most common enforcement action concerns the submission of a false 160.12 compliance statement where the submitter attests that a study was conducted in accordance with GLP regulations, but deviations were found during the inspections. If this statement is false, a civil or criminal enforcement response may be pursued by the Agency. There are no other bases for initiating an enforcement action for a violation of the GLP regulations. In the case of missing raw data, an enforcement action can be initiated for violating 40 CFR Part 169. GLP violations can result in the rejection of a study by EPA and, therefore, a denial of a registration application.

Incoming Communication:

From: [redacted] Ex 6
Sent: Saturday, February 28, 2015 6:55 AM
To: [redacted] Ex 6
Subject: GLP Certification

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Good day! I am very sorry to tell you that we would not put the study of glyphosate

EX6 = Exemption 6

ammonium in your lab. Because the Korea client tell us that the Korea Authority only accept the report with GLP certificate when evaluation. We decide to choose OECD GLP Lab. Thank you very much for your work. I hope we can cooperate next time.

Yours sincerely,

[redacted]arket & Registration Division Ex6

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Best regards

[redacted] Ex 6

Ex6 = Exemption 6